PB85-134393

Guidance for the Reregistration of Pesticide Products Containing Nuclear Polyhedrosis Virus of Heliothis ZEA as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

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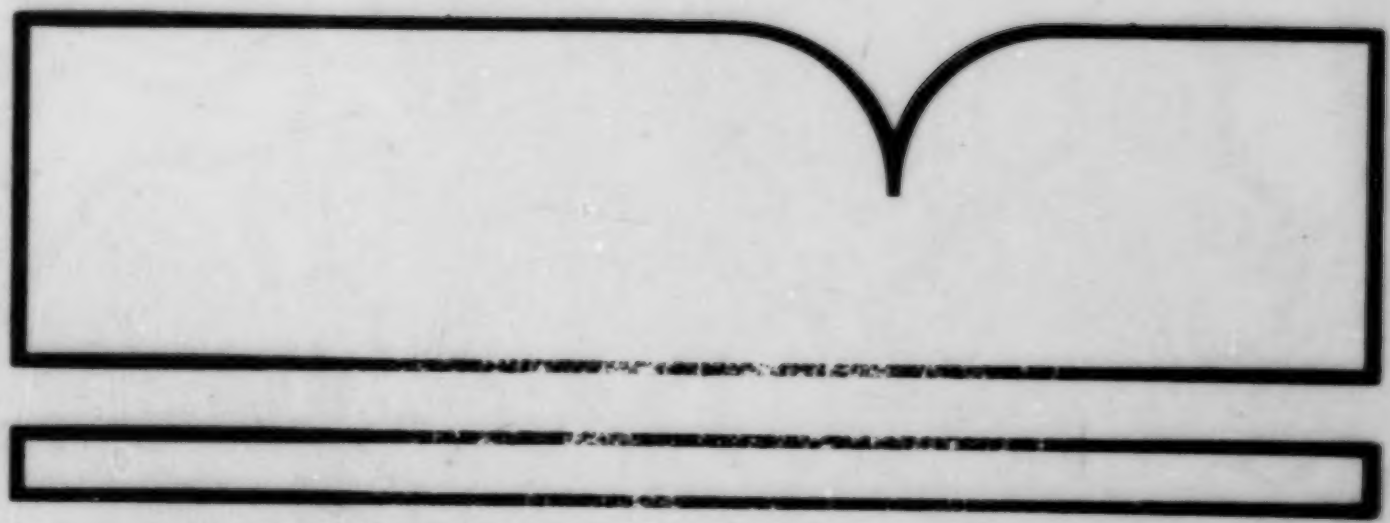

U.S. Department of Commerce
National Technical Information Service
NTIS

PB85-134393

Guidance for the Reregistration of Pesticide Products Containing Nuclear Polyhedrosis Virus of Heliothis ZEA as the Active Ingredient

June 1984

Office of Pesticide Programs
Registration Division

Environmental Protection Agency
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16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages 73
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(See ANSI-Z39.18) See Instructions on Reverse

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g)), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing-use product of the active ingredient that wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements designed to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those

registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use producers (basic suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request to the Agency to discontinue the registration of any of your products subject to the requirements of this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this document.

Registrants are reminded that §6(a)(2) of FIFRA requires you <u>at any time</u> to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible unreasonable adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	To continue registration, labeling, packaging and data requirements must be satisfied in accordance with this document.
B. Multiple Active Ingredient Products	Generic data, as described in this document will be required to continue the registration of the active ingredient under review and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the envrionment will these products be subject to the requirments of this document. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notice.

* Registrants of End-use products that also produce a manufacturing-use product must fulfill the requirements specified in this document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION

A. Introduction

This guidance document describes the Agency's current regulatory position regarding continued registration of manufacturing use products (MPs) and end-use products (EPs) containing the insecticide Heliothis zea NPV. The Agency's position is based on an evaluation of all registered products with Nuclear Polyhedrosis Virus of Heliothis zea as the sole active ingredient. This document considers known microbial and toxicological properties of this viral agent as well as established exemptions from the requirements of tolerances on all raw agricultural commodities, food and feed,and provisions for quality control, including identification. From these considerations the Agency sets forth the data and labeling requirements that must be met by registrant and applicants of Heliothis zea NPV products in order for the products to be registered or reregistered under this document. To be registrable under this document, MPs and EPs must list Nuclear Polyhedrosis Virus of Heliothis Zea as the sole active ingredient. The tables accompanying this document list the data gaps which must be satisfied through submission of additional information. Future MPs and EPs which differ appreciably from those described in this document may require that amendments be made to the document to reflect the differences.

B. Description of Chemical and Use Profile

Heliothis zea NPV is a double stranded polyhedral DNA virus that is enclosed in a nucleocapsid in the polyhedrosis inclusion body of Heliothis zea NPV. Its molecular weight is estimated to be 30×10^6 to 90×10^6 daltons.

C.A.S. #2401-948-01;Shaughnessy #107301.

This viral agent is produced in the United States solely by Zoecon Industries, a subsidiary of Sandoz Inc.

There are no federally registered MPs containing Heliothis zea NPV. There is one federally registered EP which contains Heliothis zea NPV as the sole active ingredient. It is commercially formulated into a 0.4% wettable powder containing a minimum of 4 billion polyhedral inclusion bodies per gram of product.

Polyhedral Inclusion Bodies (PIB) of Heliothis Nuclear Polyhedrosis Virus is also an accepted common name for Nuclear Polyhedrosis Virus of Heliothis zea. The trade names and other names include Biotrol VHZ, which was distributed by Nutrilite Products, Inc. and Thompson-Hayward Chemical Company, and which International Mineral and Chemical Corporation distributed as Viron/H. International Mineral Company sold this product to Sandoz, Inc. Nutrilite Products and Thompson-Hayward Chemical Company no longer have registrations. Only Sandoz, Inc. with its subsidiary Zoecon Corporation produce and distribute

nuclear polyhedrosis virus of Heliothis zea, which they do under the trade name of Elcar.

The inclusion bodies of Heliothis zea NPV are refractile, crystal-like, and polyhedral shaped. Their average diameter is about 0.86 microns; the diameter ranges in size from about 0.39 to 1.62 microns. The average dimensions of the virions after release by alkaline extraction from inclusion bodies are 190 by 32 millimicrons. Occluded rods average about 320 by 90 millimicrons. Each inclusion body contains an average of 26 virions; the range is 17 to 54 virions.

The uses include all preharvest applications to raw agricultural commodities at no preharvest interval through 0.001 pound per acre for foliar application. The specific crops that the current registration lists are: beans, corn, cotton, lettuce, peanuts, sorghum, soybeans, strawberry, tobacco and tomato. There is only one regular registration and only one 24 (c) registration,both are by Zoecon Industries, a subsidiary of Sandoz,Inc.

C. Regulatory Position

Based on a review and evaluation of all available data and other relevant information on NPV of Heliothis zea, the Agency has made the following determinations:

1. MPs and EPs containing Nuclear Polyhedrosis Virus of Heliothis zea may be registered for sale, distribution and use, subject to the terms and conditions specified in this Standard.
2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of NPV of Heliothis zea specified in this Standard. However, gaps in the data base prevent the completion of the Agency's risk assessment of this viral agent.
3. Because inclusion bodies of the virus are ubiquitous in nature and are adsorbed on soil particles, very little movement in soil is indicated, therefore groundwater is not expected to be contaminated by infiltration of virus particles through the soil profile.
4. There are no acceptable infectivity/pathogenicity data available to assess the potential hazards to nontarget terrestrial and aquatic wildlife from use of the Heliothis NPV on crops. To address

the hazards, the Agency requires results from six Tier I non-target organism tests as noted in Table A.

5. Registrants must provide or agree to develop additional data, as specified in the tables in this guidance document, to maintain existing registrations or to obtain new registrations of substantially similar products.

6. The quality control testing procedures as previously stated must also be provided to maintain existing registrations or new registrations, and exemptions from the requirements of a tolerance

D. Regulatory Rationale

The Agency has reviewed the available data concerning product analysis, environmental, toxicology and ecological effects. The Agency has determined that registration of nuclear polyhedrosis virus of Heliothis zea should continue.

An exemption for the requirement of a tolerance was granted for residues in or on all raw agricultural commodities including: corn, cottonseed, beens, lettuce, okra, peppers, sorghum, soybeans, strawberries, tobacco and tomatoes.

Since the current micribial/biochemical guidelines were not available at the time of the original registration,tests done on NPV of Heliothis zea were similar to those conducted for conventional pesticides, and some were the same as those currently required for viral pesticides.

These studies included:

a. Intravenous, Intraperitoneal, Intracerebral, and Subcutaneous Injections

b. An In Vitro Tissue Culture Studies

c. A Chronic Feeding Study

d. A Teratogenicity Study

e. An Oncogenicity Study

f. A Rhesus Monkey Study

g. A Human Feeding Study

There were no deleterious effects indicated by any of these tests. The Human Feeding Study examination gave no suggestion of viral inflammation,infection allergy or side effects to the human volunteers.

Health Monitoring of Workers Associated with Heliothis NPV Production

There were no observable deleterious effects indicated by any of the many different Health Monitoring tests run on various employees of several different companies at over a period of as much as 4 1/2 years.

Serological studies were done for the detection of antibodies specific to Heliothis zea of Nuclear Polyhedrosis Virus in human serum by hemagglutination-inhibition neither clinical symptomotogy,nor mmune response indicated subclinical infection of Heliothis zea NPV appears to have had no observable adverse effects on the general health of employees in handling the viral product.

In summary, the Agency has concluded that it can continue the registration for this viral agent for the following reasons:

1. Adequate data are available to assess the acute oral, inhalation and dermal toxicological and other biological effects of this viral agent on humans.

2. The review and evaluation of the available data and other information does not raise prudent concerns of unreasonable adverse effects of Heliothis zea , as registered. It has been concluded that this product may be used, as presently registered and labeled ,and that this product does not warrant additional regulatory action at this time.

3. Under FIFRA, the Agency cannot cancel or withhold registration merely for the lack of certain data (See sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, issuance of this standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of NPV of Heliothis zea.

E. Criteria for Registration Under This Standard

This guidance document covers all manufacturing-use and end-use products that contain Nuclear polyhedrosis virus of Heliothis zea as the sole active ingredient. Registrants and applicants for registration of such products must comply with all terms and conditions described herein. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Also, registrants and applicants for registration must follow the instructions contained in the document and complete and submit the appropriate forms within the specified time frame.

F. Acceptable Ranges and Limits

1. Product Composition Standards

To be fully covered under this document, MPs and EPs must contain Nuclear Polyhedrosis Virus of Heliothis zea as the sole active ingredient. Each product formulation proposed for registration must be fully described as indicated in the data tables with the appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider for registration any MPs and EPs provided the product is supported by toxicity, infectivity and pathogenicity data and the labeling for the product bears appropriate precautionary statements for microbial pesticides.

3. Use Patterns

To be registered under this document, end-use products containing Nuclear polyhedrosis virus of Heliothis zea must be labeled for use on all raw agricultural

commodities as specified in 40 CFR §180.1027 and MPs must be labeled to allow for formulation into EPs which are intended for use on EPA accepted uses. The attached index entry lists all registered uses, as well as approved maximum application rates and frequencies.

Terrestrial Food/Feed Use

Beans, corn, cotton, lettuce, okra, peanuts, peppers, sorghum, soybeans, strawberry, and tomatoes.

Terrestrial Non-Food

Tobacco

G. Required Labeling

All MPs and EPs containing Nuclear polyhedrosis virus of Heliothis zea must bear appropriate labeling as specified in 40 CFR 162.10, in addition to the following specific labeling requirements.

1. Labeling Requirements for Manufacturing-Use Products

a. Ingredient Statement

The ingredient statment for MPs must list the active ingredient as:

Nuclear Polyhedrosis Virus of Heliothis zea ----xx%

and contains 4 billion PIB's/gram.

b. Use Pattern Statement

All MPs must state that they are intended only for formulation into end-use products for any of the use

patterns listed below. A limiting factor will be the data that support each use pattern. No use may be included on the label where the registrant fails to agree to comply with the data requirements in either TABLE A or TABLE B for that use pattern.

c. Environmental Hazard Statement

The statement, "Do not discharge effluent containing this product directly into lakes,streams ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environment Protection Agency."

2. Labeling Requirements for End-Use Products

a. Ingredient Statement

The ingredient statement for EPs must list the active ingredient as:

Nuclear Polyhedrosis Virus of Heliothis zea ------xx%.

Contain 4 billion PIB's/gram.

b. Environmental Hazard Statement

Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of waste.

H. Tolerance Reassessment

An exemption from the requirement of a tolerance has been established for Nuclear polyhedrosis virus of Heliothis zea on all raw agricultural commodities under 40 CFR §180.1027.

(a) For the purposes of this section the viral insecticide must be produced with an unaltered and unadulterated linoculum of Heliothis zea nuclear polyhedrosis virus. The integrity of the seed virus must be assured by periodic checks, with the latest methods as indicated by this Standard.

(b) Each lot of active ingredient of the viral insecticide shall have the following specifications:

(1) The level of extraneous bacterial contamination of the final unformulated viral insecticide will not exceed 10^7 colonies per gram as determined by an aerobic plate count on trypticase soy agar.

(2) Pathogens, e.g., Salmonella, Shigella, or Vibrio must be absent.

(3) Safety to mice as determined by standardized intraperitoneal injections and and a standardized 21-day feeding study must be demonstrated.

(4) Integrity of the viral product as determined by the most sensitive and standardized serological test must be demonstrated.

(c) Exemptions from the requirement of a tolerance are established for the residues of the microbial insecticide nuclear polyhedrosis virus of Heliothis zea, as specified in paragraphs (a) and (b) of this section, in or on all raw agricultural commodities including: corn, cottonseed, beans, lettuce, okra, peppers, sorghum, soybeans, tobacco, and tomatoes.

A wide variety of toxicity studies have been used in support of this exemption from the requirement of a tolerance. These data included:

a. A chronic feeding study:

No toxicological effects were associated with ingestion of the Nuclear Polyhedrosis Virus of Heliothis zea from the test animals.

b. A teratology study:

There were no significant differences in the maternal body weight gain, and the mean fetal weight found between the treated and control groups.

c. An oncogenicity study:

Negative oncogenic effects were observed at the level tested.

d. Rhesus monkey study:

No viral infectivity of H. zea NPV was found in the lymph node tissues and blood samples of the treated monkeys. In addition, body temperature and blood chemistry values from the treated monkeys were normal.

e. Human feeding study:

This examination gave no suggestion of viral inflammation, allergy or side effects to the human volunteers.

f. Health Monitoring of Workers Associated with Heliothis NPV Production:

Heliothis zea NPV appeared to be without observable effect to the general health of employees in handling the viral product.

Conclusion: Judging from the data reviewed to date there appears to be few adverse effects to man or the environment resulting from use of this viral pesticide, NPV of Heliothis zea.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies these data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified in an attachment to the cover letter accompanying this document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982, in 47 Federal Register 53192.

All Tier I ecological effects data must be done on the technical grade material unless there is an acceptable rationale as to why it should not be done.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3).*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with its conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols

*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed EPA of the intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers considers your request, you must strive to meet the deadline for submitting the required data.

TABLE A

GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

§158.165 MICROBIAL PESTICIDE DATA REQUIREMENTS

Guideline Citation and Name of Test	Test[1]/ Substance	Guidelines Status	Are Data Required? [2]/[3]/ Yes	No	Footnote Number
§158.165 Product Analysis for Microbial Agents					
151-10, 20 Product identity	TGAI	R	[X]	[ ]	
151-11, 21 Manufacturing process	TGAI	R	[X]	[ ]	
151-12, 22 Discussion of formation of unintentional ingredients	TGAI	R	[X]	[ ]	
151-13, 23 Analysis of samples			[X]	[ ]	
151-15, 25 Certification of inerts			[X]	[ ]	
151-16 Analytical methods	TGAI	R	[X]	[ ]	
151-17, 26 Physical and chemical properties:	TGAI	R	[X]	[ ]	
Color	TGAI	R	[X]	[ ]	
Odor	TGAI	R	[X]	[ ]	
Density or Specific Gravity	TGAI	R	[X]	[ ]	
Corrosion Characteristics	TGAI	R	[X]	[ ]	

Key: R = Required data; CR = Conditionally required data; TGAI = Technical grade of the active ingredient. MP=Manufacturing use product; EP= End-use product,(TGAI=MP=EP)

1/ All data must be submitted on all of the above required tests no later than August 1986 .

2/ Data maybe referenced or cited, if previously submitted.

3/ Updated product analysis (identification) are required for this Standard to maintain the tolerance exemption and for the registration or reregistration of the product.

TABLE A

GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

§158.165 MICROBIAL PESTICIDE DATA REQUIREMENTS

Guideline Citation and Name of Test	Test[1] Substance	Guidelines Status	Are Data Required? Yes	Are Data Required? No	Footnote Number
§158.165 Product Analysis for Microbial Agents (continued)					
151-18, 27 Submittal of samples	TGAI/EP	[R]	[X]	[ ]	

1/ There are no currently establish TGAI,MP or EP each equals each other (TGAI = MP= EP), hence the purist grade of the product is what normally would be considered technical and tests should technical and tests should be performed on it.

TABLE A
GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticides-Residue Data Requirement For Microbial Agents	Composition	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Footnote Number
§158.165 Microbial Agents Residue Chemistry		N/A	N/A	N/A	1

1/ Residue data requirements shall apply to microbial pest products when Tier II or Tier III toxicology are required as specified in Toxicology table A for microbial agents. Reference C Table - Sections 158.50 and 158.100, Federal Register Vol. 47, No. 227, Wednesday, November 24, 1982, Proposed Rules, which indicates which test would trigger residue data requirments.

TABLE A
GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticide Toxicology Data Requirements And The Substances To Be Tested		Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.165 Toxicology: Microbial agents						
Acute oral						
Tier 1:						
152-30	Acute oral	EP/MP/TGAI	A,B	Yes*	00067550 00091306	No
152-31	Acute dermal	EP/MP/TGAI	A,B	Yes *	00082221 00081441	No
152-32	Acute inhalation	EP/MP/TGAI	A,B	Yes *	00081440 00075283 00089268 00065851	No[1/]
152-33	I.V., I.V., I.P injection	TGAI/EP	A,B	Yes *	00081436 00081439 00082220 00062591 00089268 00065851	No[2/]
152-34	Primary dermal	MP/EP	A,B	Yes *	00075283	No
152-35	Primary eye	MP/EP	A,B	No		Yes
152-36	Hypersensitivity study	MP/EP	A,B	Yes *	00081450 00082223 00062582	No[3/]

*

TABLE A
GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticide Toxicology Data Requirements And The Substances To Be Tested	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.165 Toxicology: Microbial agents (continued)					
152-37 Hypersensitivity-Human	MP/EP	A,B	Yes	00065898* 00070481* 00081449* 00082091*	No[3]
152-38 Cellular immune response	TGAI/EP	A,B	No	00101026* 00081442* 00067552* 00101020* 00101041* 00101040*	No[3]
152-39 Tissue Culture	TGAI/EP	A,B	Partially	00101029* 00062583*	No[4]
Tier II:					
Acute oral	MP	A,B	No		N/A[5]
Acute inhalation	MP	A,B	No		N/A[6]
Subchronic oral	TGAI	A,B	No		N/A[7]
Acute I.P., I.C	TGAI	A,B	No		N/A[8]
Primary dermal	TGAI	A,B	No		N/A[9]
Primary eye	TGAI	A,B	No		N/A[10]
Cellular immune response	TGAI	A,B	No		N/A[11]
Teratogenicity	TGAI	A,B	Yes	00065851*	No[12]

TABLE A
GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticide Toxicology Data Requirement And The Substances To Be Tested	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.165 Toxicology: Microbial agents (continued)					
Virulence enhancement	TGAI	A,B	No		N/A[13/]
mammalian mutagenicity	TGAI	A,B	No		N/A[14/]
Tier III:					
Chronic feeding	TGAI	A,B	Yes	00081436* 00089268* 00081438* 00075280* 00081437* 00089265* 00101003* 00101036* 00070480* 00082090*	No[15/]
Oncogenicity	TGAI	A,B	Yes	00065851* 00062581* 00065900* 00101018* 00062580* 00062579* 00047589* 00101028*	No[16/]
Mutagenicity	TGAI	A,B			N/A
Teratogenicity	TGAI	A,B	No		N/A

TABLE A

GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticide Toxicology Data Requirement And The Substances To Be Tested	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Footnotes Number
§158.165 Toxicology: Microbial agents (continued)						
ADDITIONAL TOXICOLOGY STUDIES: (Data Not Required)						
Human Feeding Study	TGAI	A,B	Yes	00062588* 00044040* 00075281* 00081461* 00070487*	No	
Rhesus Monkey Study	TGAI	A,B	Yes	00090423*	No	

(Footnotes)

(1) Required if 20 percent or more of the aerodynamic equivalent of the product (as registered or under conditions of use) is composed of particulates under 10 microns in diameter.

(2) Data required for products as follows: (i) intravenous ("IV") infectivity study for viral agents; (ii) intracerebral ("IC") infectivity study for viral agents.

TABLE A

GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticide Toxicology Data Requirement And The Substances To Be Tested	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?

(Footnotes continued)

(3) Required if commonly recognized use practices will result in repeated human contact by inhalation or dermal routes.

(4) Data required for products whose active ingredient is a virus.

(5) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus) is observed in the test animals treated in the Tier 1 acute oral infectivity tests.

(6) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus) is observed in the test animals treated in the comparable Tier I acute inhalation tests.

(7) Required if marked edema or broad erythema was observed in the Tier I dermal irritation study.

(8) Required if severe ocular lesions are observed in the Tier I primary eye irritation study.

(9) Required if results of the Tier I cellular immune response test indicate abnormalities.

(10) Required when Tier I test on viral agents shows replication of the virus in mammalian hosts and significant damage to mammalian cells.

(11) Required if any of the following criteria are met: (i) Acute infectivity tests are positive in Tier I studies: (ii) Adverse cellular effects are observed in cellular immune response studies; or (iii) Positive results are obtained in tissue culture tests with viral agents.

(12) Required when the potential for chronic adverse effects (e.g., replication or persistence of viral or subviral constituents) are demonstrated by any of the Tier II tests (except primary dermal, primary ocular, and mammalian mutagencity tests).

(13) Required when the potential for oncogenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, or mutagenic effects) by any of the Tier II tests except the primary dermal and primary ocular studies.

*All data was submitted by or purchased by SANDOZ, INC. whose subsidiary ZOECON, INDUSTRIES now controls the only registered product containing this active ingredient.

TABLE A
GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticide Toxicology Data Requirement And The Substances To Be Tested	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?

(Footnotes continued)

(14) Required when the potential for mutagenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents) by any of the Tier II tests except primary dermal or primary ocular studies.

(15) Required when the potential for teratogenic effects is expected based on the presence or persistence of fungi, viruses in mammalian species as a result of testing performed in Tier II, except primary dermal and primary ocular studies.

(16) Data submitted in support of registering NPV of Heliothis zea was by conventional data requirements for registration as the "biorational guidelines" had not been promulgated (1975). Now these data are not needed.

(17) Required when the potential for mutagenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents) by any of the Tier II, except primary dermal or primary ocular studies.

(18) Required when the potential for teratogenic effects is expected based on the presence or persistence of viruses in mammalian species as a result of testing performed in Tier II, except primary dermal and primary ocular studies.

(19) These data are not required for this active ingredient (NPV of Heliothis zea).

TABLE A

GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

Microbial Pesticide Data Requirements		Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.165 Nontarget organisms and environmental expression: Microbial agents						
Tier I:						
154-16	Avian oral	TGAI	A,B	No		Yes
154-17	Avian injection test	TGAI	A,B	No		Yes
154-18	Wild mammal testing	TGAI	A,B	No		No
154-19	Freshwater fish testing	TGAI	A,B	No	00082222*	Yes
154-20	Freshwater aquatic invertebrate testing	TGAI	A,B	No		Yes
154-21	Estuarine and marine animal testing	TGAI	A,B	No[3]/	00082222*	No
154-22	Plant studies	TGAI	A,B	No		No
154-23	Nontarget insect testing	TGAI	A,B	No		Yes
154-24	Honey bee testing	TGAI	A,B	No		Yes

Key: 1/ TGAI = Technical grade of the active ingredient; EP = End-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food.
3/ Not required by current use pattern.

TABLE B

GENERIC DATA REQUIREMENTS FOR NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

§158.165 MICROBIAL PESTICIDE DATA REQUIREMENTS

Guideline Citation and Name of Test	Test Substance[1]/	Guidelines Status	Are Data Required?[2]/[3]/ Yes	No	Footnote Number
§158.165 Product Analysis for Microbial Agents					
151-10, 20 Product identity	TGAI	R	[X]	[ ]	
151-11, 21 Manufacturing process	TGAI	R	[X]	[ ]	
151-12, 22 Discussion of formation of unintentional ingredients	TGAI	R	[X]	[ ]	
151-13, 23 Analysis of samples			[X]	[ ]	
151-15, 25 Certification of inerts			[X]	[ ]	
151-16 Analytical methods	TGAI	R	[X]	[ ]	
151-17, 26 Physical and chemical properties:	TGAI	R	[X]	[ ]	
Color	TGAI	R	[X]	[ ]	
Odor	TGAI	R	[X]	[ ]	
Density or Specific Gravity	TGAI	R	[X]	[ ]	
Corrosion Characteristics	TGAI	R	[X]	[ ]	

Key: R = Required data; CR = Conditionally required data; TGAI = Technical grade of the active ingredient.

1/ All data must be submitted on all of the above required tests no later than August 1986.

2/ Data may be referenced or cited, if previously submitted.

3/ Updated product analysis (identification) are required for this Standard to maintain the tolerance exemption and for the registration or reregistration of the product.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NUCLEAR POLYHEDROSIS VIRUS OF HELIOTHIS ZEA

§158.165 MICROBIAL PESTICIDE DATA REQUIREMENTS

Guideline Citation and Name of Test	Test Substance[1]	Guidelines Status	Are Data Required?[2][3] Yes	No	Footnote Number
§158.165 Product Analysis for Microbial Agents (continued)					
151-18, 27 Submittal of samples	TGAI	[R]	[X]	[ ]	

1/ R = Required data; CR = Conditionally required data; TGAI = Technical grade of the active ingredient; MP = Manufacturing use product; EP = end-use product. (There are no currently established TGAI or MP each equals each other (TGAI = MP = EP); hence, the purest grade of the product is what is normally considered technical material and tests should be performed with it.)

2/ All data must be submitted on all of the above required tests no later than August 1986. Data may be referenced or cited, if previously submitted.

3/ Updated product analysis (identification) are required for this Standard to maintain tolerance exemption an for the registration or reregistration of the product.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c))], packaging [40 CFR §162.16], and labeling [40 CFR 162.10, Appendix V-2 and IV-2], as indicated by the following paragraphs of this chapter of the guidance document.

You must submit the revised labeling set forth in this guidance package within 90 days of receipt of this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-2) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-2. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-2. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-2. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No." or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-2. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est.," is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-2. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-2. [40 CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-2. [40 CFR §162.10(h)(1)(ii)]

c

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-2. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-2. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-2. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See appendix V-2. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-2. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-2. [40 CFR §162.10(h)(2)(i)

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms, excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-2. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flash-point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following critera:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flashback; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), as determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-2. [40 CFR §162.10(1)(2)(ii)]

Item 10. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-4 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-2. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which all referred to on the label or which are to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be

made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Product Manager -17 (Timothy A. Gardner)
Phone No. (703) 557-2690
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1 and revised labeling. Refer to Appendix II with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1).

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Heliothis Standard

00044040 Heimpel, A.M.; Buchanan, L.K. (1965) Human Feeding Tests Using the Nuclear Polyhedral Virus of Heliothis zea. (U.S. Agricultural Research Service, Insect Pathology Laboratory, unpublished study including letter dated Sep 7, 1966 from R.S. Roe to M.W. Parker; CDL:104333-A)

00047582 Woodard, G. (1969) Proposed Protocol: NPV-Virus-Technical: Polyhedrosis Virus Safety Evaluation by a Single and Repeated Subcutaneous Injection, by a Single and Repeated Oral Administration and by Single and Repeated Inhalation Exposure in Rhesus Monkeys. (Unpublished study including letter dated Jul 7, 1970 from G. Woodard to Michael F. Markel, received on unknown date under 8G0722; prepared by Woodard Research Corp., submitted by Nutrilite Product, Inc., Buena Park, Calif.; CDL:093032-A)

00047589 Totman, L.; Bleiberg, M.J.; Cronin, M.T.I. (1968) Polyhedral Virus: Evaluation of the Carcinogenic Potential in Mice: Addendum to the Final Report. (Unpublished study received on unknown date under 8G0722; prepared by Woodard Research Corp., submitted by Nutrilite Product, Inc., Buena Park, Calif.; CDL:093032-I)

00056871 Ignoffo, C.M. (1973) Effects of entomopathogens on vertebrates. Pages 141-164, In Annals of the New York Academy of Sciences: Volume 217. By ? N.P. (Also in unpublished submission received Feb 7, 1977 under 275-18; submitted by Abbott Laboratories, North Chicago, Ill.; CDL:231528-E)

00062579 Cronin, M.T.I. (1966) Polyhedral Virus: Summary of Histopathological Observations in Dogs. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-B)

00062580 Woodard Research Corporation (19??) Polyhedral Virus: A Summary Evaluation of Observations on 20 Day Old Rat Fetuses. (Unpublished study received Oct 2, 1968 under 8G0697; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-C)

00062581 Durloo, R.S.; Bleiberg, M.J. (1967) Polyhedral Virus Evaluation of the Carcinogenic Potential in Mice. 57 to 78 week interim rept. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-D)

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Registrations Under the Heliothis Standard

00062582 Rostenberg, A., Jr. (1967) Report on the Investigation to Determine the Skin Irritancy and Potential Sensitizing Ability of the Heliothis Nuclear Polyhedrosis Virus on Humans. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Univ. of Illinois, Dept. of Dermatology, submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-E)

00062583 Rafajko, R.R. (1967) Final Report: In vitro Tissue Culture Studies with Nuclear Polyhedrosis Virus of Heliothis. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Medical Research Consultants, Inc., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-F)

00062584 International Minerals & Chemical Corporation (1967) Published and Unpublished Studies Demonstrating Specificity of Heliothis Virus to Other Insects, Invertebrates and Vertebrates Including Humans. (Unpublished study received Oct 2, 1968 under 8G0697; CDL:091209-G)

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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

Appendix IV

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				

Appendix IV
(continued)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

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ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

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PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by otner approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by snaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclonexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctanydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl pntnalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alconol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alconol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentacloropnenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetracnloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Maleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

:107301 POLYHEDRAL INCLUSION BODIES OF HELIOTHIS NUCLEAR POLYHEDROSIS VIRUS*

TYPE PESTICIDE: Biological Control Agent

FORMULATIONS: WP (0.4%) (contains a minimum of 4 billion polyhedral inclusion bodies per gram of product)

GENERAL WARNINGS AND LIMITATIONS: Maintain a pH of approximately 6 to 9 of the spray tank mixture. Do not allow the spray mixture to stand in the tank for more than 12 hours. Activity of the virus may be impaired by storage at temperatures above 80 F (26.7 C). If held beyond the current growing season, refrigerate or freeze until the following growing season.
Agricultural Crop Tolerances (other than those listed in the text):
All raw agricultural commodities (including okra and peppers) - exempt
Definitions of Terms:
Claims for pest control limited to suppression of populations are indicated by parenthesized pest name.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
AGRICULTURAL CROPS		
General Warnings and Limitations: May be applied by aircraft or ground equipment in 3 to 20 gallons of water per acre. Stickers may be added if heavy dew or rain is expected. Apply lower rates for suppression of light infestations and higher rates for suppression of moderate infestations.		
/28001AA Beans /28005AA Corn /28007AA Cotton /13020AA Lettuce /28015AA Peanuts /28019AA Sorghum /28023AA Soybeans /01016AA Strawberry /26003AA Tobacco /11005AA Tomato		Exempt No preharvest interval through 0.001 pound per acre for foliar application.
ITBCBOC (Corn earworm/ Tomato fruitworm/ Bollworm (larvae)) ITBCBNC (Tobacco budworm (larvae))	0.125-0.25 lb 0.4% WP/A (0.4% WP)	Foliar application. Apply at first sign of newly hatched larvae and repeat at 3 to 7 day intervals as long as egg deposition continues. Thorough coverage is essential for control.

*Elcar
Heliothis nuclear polyhedrosis virus

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POLYHEDRAL INCLUSION BODIES OF HELIOTHIS NUCLEAR POLYHEDROSIS VIRUS

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Beans cluster (continued)		
		0.0625-0.125 lb 0.4% WP/A (0.4% WP)	Foliar application. Apply at first sign of newly hatched larvae and repeat at 3 to 7 day intervals as long as egg deposition continues. Tank mix with Bacillus thuringiensis.
ITBCBOC ITBCBNC	(Cotton) (Corn earworm/ Tomato fruitworm/ Bollworm (larvae)) (Tobacco budworm (larvae))	0.0625-0.125 lb 0.4% WP/ 3-5 gal/A (0.4% WP)	Foliar application. Apply by aircraft. Apply at first sign of egg deposition or newly hatched larvae. Repeat at 3 to 5 day intervals to sustain suppression or until adequate larval reduction is achieved. Tank mix with chlordimeform.

AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS

9001500 AAAAAAA	Aerial Application		
	--		Refer to AGRICULTURAL CROPS All sites
9900300 AAAAAAA	Tank Mix		
	--		Refer to AGRICULTURAL CROPS All sites

POLYHEDRAL INCLUSION BODIES OF HELIOTHIS NUCLEAR POLYHEDROSIS VIRUS

Listing of Registered Pesticide Products by Formulation

0.4% wettable powder

polyhedral inclusion bodies of heliothis nuclear polyhedrosis virus (107301)
011273-00017

POLYHEDRAL INCLUSION BODIES OF HELIOTHIS NUCLEAR POLYHEDROSIS VIRUS

Appendix B

Listing of Registration Numbers By Site

/28001AA	Beans	011273-00017
/28005AA	Corn	011273-00017
/28007AA	Cotton	011273-00017
/13020AA	Lettuce	011273-00017
/28015AA	Peanuts	011273-00017
/28019AA	Sorghum	011273-00017
/28023AA	Soybeans	011273-00017
/01016AA	Strawberry	011273-00017
/26003AA	Tobacco	011273-00017
/11005AA	Tomato	011273-00017